IN THE UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

MICHAEL and KELLY YURCIC, Plaintiffs, v. PURDUE PHARMA, L.P., PURDUE PHARMA, INC., PURDUE FREDERICK COMPANY, ABBOTT LABORATORIES, ABBOTT LABORATORIES, INC., MORTON RUBIN, M.D., and HOWARD R. CORBIN, M.D., Defendants.	Case No. 02-3737

PURDUE AND ABBOTT'S JOINT MEMORANDUM OF LAW
IN OPPOSITION TO PLAINTIFFS' MOTION TO REMAND

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Defendants, Purdue Pharma L.P., Purdue Pharma Inc., The Purdue Frederick Company (collectively, "Purdue"), and Abbott Laboratories and Abbott Laboratories, Inc. (collectively, "Abbott"), respectfully submit this Joint Memorandum of Law in Opposition to Plaintiffs' Motion to Remand.[1]

PRELIMINARY STATEMENT

This is a products liability action arising from injuries allegedly caused by OxyContin® Tablets ("OxyContin"), a federally-regulated, Schedule II, opioid-based prescription pain medication manufactured, marketed and distributed by Purdue and co-promoted by Abbott. In their Complaint ("Compl."), Plaintiffs level a multitude of allegations against Purdue and Abbott for alleged wrongdoing in the "design, manufacture, testing, promotion, advertising, warning, labeling, marketing and sale of OxyContin." (Compl. ¶ 95.) According to Plaintiffs, Purdue and Abbott engaged in an "aggressive marketing strategy" that "relied heavily on highly coercive tactics," misrepresentations regarding the appropriate uses of OxyContin, and "fail[ure] to adequately disclose and discuss the safety issues and possible adverse effects of OxyContin use." (Compl. ¶ 30.) The Complaint further alleges that Purdue and Abbott should be liable because OxyContin is defectively designed. (See, e.g., Compl. ¶¶ 35-38 (alleging OxyContin fails to provide adequate relief); Compl. ¶¶ 48, 50 (alleging Purdue and Abbott failed to formulate and reformulate OxyContin to prevent abuse and misuse).)

Although it is clear from these and similar allegations that Purdue's and Abbott's purported liability constitutes the gravamen of this action, the Complaint also names two non-

[1] Defendants removed this action to this Court on June 12, 2002. On or about July 2, 2002, Plaintiffs served a Motion for Remand ("Pl. Mot.") with a supporting Memorandum of Law ("Pl. Mem.").

diverse defendants: Mortin Rubin, M.D., and Howard R. Cohen, M.D. (collectively, the "doctor defendants"). (See Compl. ¶¶ 14, 16.) Plaintiffs' inclusion of these defendants, however, does not deprive the Court of diversity jurisdiction. Rather, the Complaint clearly demonstrates that the claims against the doctor defendants are time-barred, compelling the conclusion that they were fraudulently joined.

Specifically, Plaintiffs allege that *more than two years prior* to commencing this action:

- Mr. Yurcic agreed to, and in fact did, enroll in an in-patient detoxification program at the Caron Foundation "for treatment of his addiction to OxyContin" (Compl. ¶¶ 76, 77);
- Mr. Yurcic was placed on a six-month "narcotic withdrawal plan" which he was unable to complete because he had used his two-week supply of OxyContin in one week (Compl. ¶¶ 75, 76);
- Mr. Yurcic was admitted to Holy Spirit Hospital as a result of "Michael Yurcic's suspected overdosing of OxyContin" and was transferred to Healthsouth Rehabilitation of Mechanicsburg for continued care (Compl. ¶¶ 60, 61, 64);
- Mr. Yurcic was "nauseated, vomiting and felt confused from taking a lot of OxyContin" (Compl. ¶ 57); and
- Ms. Yurcic discovered that 33 of the 50 OxyContin immediate-release tablets and ten OxyContin time-release tablets that Mr. Yurcic received on March 4, 1999 (one day previously) were missing (Compl. ¶ 59).

Subsequent to removal, Plaintiffs attempted to resurrect their patently untimely claims by embellishing the allegations against the doctor defendants in their remand brief. Incredibly, Plaintiffs now write that Mr. Yurcic did not know he was addicted to OxyContin until January 17, 2000, the time of his *release* from the in-patient detoxification program. (Pl. Mot. ¶ 11; Pl. Mem. at 5.) Nowhere is this allegation made in the Complaint, and in fact, it is

contradicted by, e.g., Plaintiffs' allegation that they met and spoke with Dr. Albert Zanetti on December 17, 1999 regarding treatment for Mr. Yurcic's addiction to OxyContin. (Compl. ¶ 76.) In any event, apart from its factual incredulity, this feckless attempt to evade diversity jurisdiction also fails as a matter of law. It is well-settled that a court must evaluate fraudulent joinder on the basis of the complaint at the time of removal. Where, as here, the initial pleadings do not support a viable claim against the non-diverse defendants, a finding of fraudulent joinder must follow.

Plaintiffs' maneuvering does not stop there. As an additional obstacle to this Court's jurisdiction, Plaintiffs attempt to obscure the fundamental nature of their claims, which necessarily arise under federal law. These tactics are nothing more than improper attempts to divest this Court of jurisdiction and deprive Defendants of their right to litigate in a federal forum. The motion to remand should be denied.

ARGUMENT

I. THIS COURT HAS DIVERSITY JURISDICTION

Federal courts have an obligation to exercise the jurisdiction that has been conferred on them. See, e.g., New Orleans Pub. Serv. Inc. v. Council of New Orleans, 491 U.S. 350, 358-59 (1989); Alabama S. Ry. Co. v. H.C. Thompson, 200 U.S. 206, 218 (1906) ("[f]ederal courts may and should take such action as will defeat attempts to wrongfully deprive parties entitled to sue in the [f]ederal courts of the protection of their rights in those tribunals"). Removal is proper, and a motion to remand should be denied, where there is complete diversity of citizenship among the parties and the amount in controversy exceeds $75,000, exclusive of interests and costs. See 28 U.S.C. §§ 1332(a)(1), 1441; see also In re General Motors Corp.

Pickup Truck Fuel Tank Prods. Liab. Litig., MDL No. 961, Civ. No. 93-1811, 1993 WL 147245 (E.D. Pa. May 5, 1993) (Yohn, J.) ("[S]ince the basis for removing this action was diversity jurisdiction, which is not discretionary, the court will not and cannot exercise its discretion and remand this action to state court.").

An exception to the complete diversity requirement occurs where plaintiffs make claims against non-diverse defendants despite the fact that no cause of action can be established against those parties. Under the doctrine of fraudulent joinder, such defendants are disregarded for diversity jurisdiction purposes if "there is no reasonable basis in fact or colorable ground supporting the claim[s]" against them. See Cipriani v. Federal Ins. Co. Div. of Chubb Group of Ins. Cos., No. Civ. A. 99-CV-1014, 1999 WL 554601, at *2 (E.D. Pa. July 20, 1999) (Kauffman, J.) (citations omitted). This determination must be made on the basis of the complaint *at the time of removal*. See, e.g., Spring-Ford Area Sch. Dist. v. Genesis Ins. Co., 158 F. Supp. 2d 476, 479, 482 (E.D. Pa. 2001) (Yohn, J.) (rejecting plaintiffs' attempt to recast claims against instate defendants in the motion to remand). No actual fraud is required for a finding of fraudulent joinder. See id. at 484 n.3.

The fraudulent joinder doctrine has been applied by federal courts in the Third Circuit to non-diverse defendants in complex products liability actions. See In re Diet Drugs Prods. Liab. Litig., No. 1203, CIV. 99-20078, 1999 WL 554608 (E.D. Pa. June 29, 1999) ("Diet Drugs I") (Bechtle, J.); In re Diet Drugs Prods. Liab. Litig., Nos. MDL 1203, Civ. A. 99-20186, 2000 WL 1886594 (E.D. Pa. Dec. 7, 2000) ("Diet Drugs II") (Bechtle, J.). It applies equally here

because, based on the facts alleged in Plaintiffs' Complaint, there is no possibility of recovery against the non-diverse defendants.[2]

A. Fraudulent Joinder of the Doctor Defendants Is Evident Because the Claims Against Them Are Time-Barred

Under Pennsylvania law, a cause of action for medical malpractice is governed by a two-year statute of limitations. 42 Pa. Cons. Stat. § 5524(2). Plaintiffs allege that the doctor defendants were negligent in *all aspects* of their treatment of Mr. Yurcic, which necessarily includes their initial prescriptions of OxyContin. (See Compl. ¶¶ 133, 144 (alleging "[t]o the extent [the doctor defendants] conducted any evaluation, examination, monitoring, treating and testing [of Mr. Yurcic], [their] performance was not reasonable and not in accordance with accepted standards of medical care").) However, the allegations of dates of treatment by those practitioners clearly show that such claims are time-barred. Plaintiffs have alleged that Dr. Rubin first prescribed OxyContin to Mr. Yurcic "on or about October 1996" (Compl. ¶ 53); ending in August 1999. (Compl. ¶ 71.) Dr. Cohen prescribed OxyContin to Mr. Yurcic "on or about March 15, 1999" (Compl. ¶ 66); he did not treat Mr. Yurcic after March 17, 1999. (Compl. ¶¶ 67, 68.)

Hence, by their own allegations, Plaintiffs' two-year statute of limitations expired *in October 1998* (as against Dr. Rubin) and *on March 15, 2001* (as against Dr. Cohen), long before

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[2] This Court has also determined that a finding of fraudulent joinder is proper where the claims against non-diverse defendants are time-barred and the statute of limitations has not been tolled. See Diet Drugs I (denying motion to remand); Miller v. Firestone Tire & Rubber Co., 581 F. Supp. 36, 37 (W.D. Pa. 1984) (Weber, J.) (denying motion to remand where claims against in-state defendant were time-barred). The same result should obtain here.

Plaintiffs commenced this action on January 4, 2002. Plaintiffs' claims against the doctor defendants are thus time-barred.[3]

1. The Discovery Rule Does Not Apply to Mr. Yurcic's Medical Malpractice Claims and the Statute of Limitations Is Not Tolled

Plaintiffs bear the burden of establishing the applicability of the discovery rule. See Cochran v. GAF Corp., 666 A.2d 245, 249 (Pa. 1995) ("one claiming the benefit of the [discovery rule] exception bears the burden of establishing that she falls within it"); Dreischalick v. Dalkon Shield Claimants Trust, 845 F. Supp. 310, 315 (W.D. Pa. 1994) ("plaintiff has the burden of justifying *any delay* beyond the date on which the [statute of] limitation would have expired if computed from the date on which the acts giving rise to the cause of action allegedly occurred") (emphasis added); Floyd v. Brown & Williamson Tobacco Co., 159 F. Supp. 2d 823, 829 (E.D. Pa. 2001) ("plaintiff has the burden of establishing that the discovery rule should apply"). Further, prior to applying the discovery rule, a court "must . . . address the ability of the damaged party, exercising reasonable diligence, to ascertain the fact of a cause of action." Pocono Int'l Raceway v. Pocono Produce, 468 A.2d 468, 471 (Pa. 1983). Plaintiffs have failed to meet their burden.

Plaintiffs' own assertions belie any attempt to claim such an exception to the statute of limitations. In their verified Complaint, Plaintiffs allege the following relevant facts:

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[3] Because Mr. Yurcic's medical malpractice claims against the doctor defendants are time-barred, Plaintiff Kelly Yurcic's loss of consortium claims against those same defendants must fail as a matter of law because a loss of consortium claim is a derivative action that requires a valid underlying cause of action by one's spouse. See, e.g., Szydlowski v. City of Philadelphia, 134 F. Supp. 2d 636, 639 (E.D. Pa. 2001) (because wife's tort claims against certain defendants were dismissed, husband's loss of consortium claims against same defendants "must also fail"); Hepps v. General Am. Life Ins., No. CIV. A. 95-5508, 1998 WL 564497, at *7 (E.D. Pa. Sept. 2, 1998) ("where the allegedly injured spouse fails to plead a cognizable claim, his spouse's claim for loss of consortium cannot survive").

- on or about March 5, 1999, Mr. Yurcic was "nauseated, vomiting and felt confused from taking a lot of OxyContin" (Compl. ¶ 57);

- on or about March 5, 1999, Kelly Yurcic discovered that 33 of the 50 OxyContin immediate-release tablets and ten OxyContin time-release tablets that Mr. Yurcic received on March 4, 1999 (one day previously) were missing (Compl. ¶ 59);

- on or about March 8, 1999, Mr. Yurcic was admitted to Holy Spirit Hospital as a result of "Michael Yurcic's suspected overdosing of OxyContin" (Compl. ¶¶ 60, 61);

- on or about March 12, 1999, Mr. Yurcic was discharged from Holy Spirit Hospital and admitted to Healthsouth Rehabilitation of Mechanicsburg for continued care (Compl. ¶ 64);

- on or about November 19, 1999, Mr. Yurcic saw Dr. Albert Zanetti (not a party to this action), who placed Mr. Yurcic on a six-month "narcotic withdrawal plan" (Compl. ¶ 75);

- on or about December 17, 1999, Mr. Yurcic saw Dr. Zanetti again and informed him that he had used his two-week supply of OxyContin in one week (Compl. ¶ 76);

- on or about December 17, 1999, Mr. Yurcic agreed to enroll in an in-patient detoxification program (Compl. ¶ 76); and

- on or about December 27, 1999, Mr. Yurcic was admitted to the Caron Foundation "for treatment of his addiction to OxyContin" (Compl. ¶ 77).

Despite these verified allegations (which are assumed to be true in evaluating fraudulent joinder, see Diet Drugs I, 1999 WL 554608, at *1), Plaintiffs now attempt to rely upon the discovery rule to toll the commencement of the statute of limitations.[4] Remarkably, Plaintiffs take the position that Mr. Yurcic did not become aware of his alleged injuries until approximately January 17, 2000, *upon his discharge from the in-patient detoxification program*. (See Pl. Mot. ¶ 11; Pl.

[4] The discovery rule is a limited exception to the strict application of statutes of limitation that tolls the running of the statute of limitations until "the plaintiff knows *or reasonably should know* of an injury and also knows *or reasonably should know* that the injury was caused by the wrongful act of another." Floyd, 159 F. Supp. 2d at 829 (emphasis added).

Mem. at 5.)[5] This position is belied by the Complaint, which alleges that by the end of 1999, Mr. Yurcic had been admitted to a hospital due to suspected overdosing of OxyContin, admitted to a rehabilitation hospital for continued care, placed on a narcotic withdrawal plan (which he failed to successfully complete), and admitted to a detoxification program. Each of these facts *individually*, let alone taken together, provides sufficient grounds to show that Plaintiffs were aware (or should have been aware) of the alleged injuries, and the purported source of such injuries. Mr. Yurcic's failure to use reasonable diligence to discover his alleged injuries in 1999 precludes Plaintiffs' reliance on the discovery rule as a matter of law.[6] See Bradley v. Ragheb, 633 A.2d 192, 196 (Pa. 1995) ("[t]he polestar of the Pennsylvania discovery rule is not a plaintiff's actual acquisition of knowledge but whether the information, through the existence of due diligence, was knowable to the plaintiff").

Plaintiffs' new allegation that Mr. Yurcic was unable to discover his injuries until mid-January 2000 is disingenuous given the clear allegations of the Complaint to the contrary, including Mr. Yurcic's display of physical symptoms as early as March 1999 and repeated incidents involving his consumption of OxyContin in excess of the amounts prescribed. In any event, Plaintiffs do not (because they cannot) make any attempt to describe what efforts Mr. Yurcic made to discover his injuries prior to 2000 and why Mr. Yurcic was unable to do so (although the Complaint plainly evidences that Mr. Yurcic did discover, or reasonably should

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[5] Perhaps not coincidentally, the January 17, 2000 date is just shy (by two weeks) of the two-year statute of limitations.

[6] Even if this Court were to decide that the discovery rule applies and that the statute of limitations was tolled until the occurrence of any of the previously set forth incidents (all of which occurred in 1999), the medical malpractice claims would still be time-barred. Plaintiffs sat on their rights and delayed the commencement of this case until January 4, 2002, more than two years after each of those incidents.

have discovered, such injury prior to 2000). Such omissions are fatally defective to Plaintiffs' claims against the doctor defendants. See Pitts v. Northern Telecom, Inc., 24 F. Supp. 2d 437, 441 (E.D. Pa. 1998) ("plaintiff must show that she could not have ascertained the operative facts underlying her cause of action even one day earlier through an exercise of due diligence"); Bigansky v. Thomas Jefferson Univ. Hosp., 658 A.2d 423, 427 (Pa. Super. Ct. 1995) ("To come within this [discovery rule] exception, it is essential that the party has made reasonable efforts to protect his interests and explain why he was unable to discover promptly the operative facts necessary to plead his cause of action.") (internal punctuation omitted); see also Dreischalick, 845 F. Supp. at 315 (burden is on plaintiff to "allege and prove facts which show that he made reasonable efforts to protect his interests and which explain why he was unable to discover the operative facts for his cause of action sooner than he did").

Plaintiffs apparently realize the deficiency of the allegations in their Complaint as they attempt to raise new allegations (and embellish prior allegations) in their Motion to Remand. It is black-letter law, however, that Plaintiffs cannot cure these defects and "bootstrap [their] way into remand" because the viability of claims against non-diverse parties is determined by the pleadings at the time of removal. See Castner v. Exxon Co., U.S.A., 563 F. Supp. 684, 688 (E.D. Pa. 1983) (Pollak, J.) (rejecting proposed amendment to complaint proffered with remand motion as basis for claim against non-diverse defendant; remanding on other grounds); Spring-Ford, 158 F. Supp. 2d at 482 (finding fraudulent joinder where complaint did not support remand motion's characterization of claim against non-diverse defendant); Diet Drugs I, 1999 WL 554608, at *1 (stating court must focus on complaint at the time of removal in evaluating fraudulent joinder).

The most notable, and most unbelievable, of Plaintiffs' embellishments is that Mr. Yurcic did not know he was addicted to OxyContin until his *release* from the in-patient detoxification program. (Pl. Mot. ¶ 11; Pl. Mem. at 5.) This new assertion flies in the face of Plaintiffs' Complaint wherein they acknowledge that as late as December 17, 1999, Plaintiffs met with Dr. Zanetti to discuss treatment options *for his addiction to OxyContin*. (Compl. ¶ 76.) At that time, Mr. Yurcic "*agreed to enroll in an in-patient detox program*" at the Caron Foundation "*for treatment of his addiction to OxyContin*." (Compl. ¶¶ 76, 77 (emphasis added).) Even prior to these events, Mr. Yurcic was placed on a six-month "*narcotic withdrawal plan*." (Compl. ¶ 75 (emphasis added).) For Plaintiffs to come now before this Court and allege that Mr. Yurcic was not aware of his addiction until his release from the detoxification program is simply untenable.

Additionally, Plaintiffs' belated contention that until mid-January 2000, Mr. Yurcic "had no true comprehension of his addiction *as a disease*" (see Compl. ¶ 78 (emphasis added); Pl. Mot. ¶ 11, Pl. Mem. at 5) is a distinction without a difference.[7] Mr. Yurcic knew, *or should have known*, of the alleged source and nature of his injuries no later than when he agreed to enroll in and was subsequently admitted to a *detoxification program* in December 1999. See Bigansky, 658 A.2d at 430 ("once the patient is aware or should reasonably have become aware that medical treatment is causing him personal injury the statute [of limitations] begins"); Pitts, 24 F. Supp. 2d at 441 ("For a claim to accrue, the plaintiff need not know the exact medical

[7] Because the Complaint is the operative pleading for determining fraudulent joinder, the remand motion papers' other attempts to recharacterize Mr. Yurcic's allegations also fail as a matter of law. See Pl. Mem. at 4 (recasting Mr. Yurcic's purported reaction to an overdose of OxyContin (Compl. ¶¶ 59, 60) as "side affects [sic]"); Pl. Mem. at 9 (contending Mr. Yurcic's admission to "an Acute Rehab Hospital" (Compl. ¶ 64) was unrelated to his alleged addiction).

cause of an injury, that the injury was caused by another party's negligence or that he has a legal cause of action.").

It also bears emphasis that Mr. Yurcic's subjective perception of his alleged injuries is not controlling. See Pitts, 24 F. Supp. 2d at 441 (statute of limitations is only tolled by the discovery rule "if a reasonable person in plaintiff's position would not have been aware of the salient facts"). Here, Mr. Yurcic had sufficient information to discover his alleged injuries prior to January 2000. A reasonable person in Mr. Yurcic's position would have done so. His failure to do so bars the application of the discovery rule. See id. ("If a party has the means of discovery within his powers but neglects to use them, his claim will still be barred."); see also Bradley, 633 A.2d at 196 ("[f]ailure to make inquiry when information is available is failure to exercise reasonable diligence *as a matter of law*").

Because the discovery rule cannot save Mr. Yurcic's medical malpractice claims against the doctor defendants, those claims are time-barred. As a derivative claim, Kelly Yurcic's claim against the doctor defendants also must fail. Consequently, Plaintiffs do not maintain any viable causes of action against the doctor defendants. Therefore, this Court must hold that the doctor defendants were fraudulently joined by Plaintiffs solely to defeat federal diversity jurisdiction.

B. The Amount in Controversy Requirement Is Satisfied

Although district courts within the Third Circuit have utilized different standards in assessing the amount in controversy (see Sdregas v. Home Depot, Inc., Civ. A. No. 01-CV-5851, 2002 U.S. Dist. LEXIS 12159, at *8 n.5 (E.D. Pa. Apr. 4, 2002) (Kauffman, J.)), the Court of Appeals has outlined a number of rules in this regard. "The amount in controversy is not

measured by the low end of an open-ended claim, but rather by a reasonable reading of the value of the rights being litigated." Angus v. Shiley, 989 F.2d 142, 146 (3d Cir. 1993). Where, as here, the initial pleading does not limit the amount of damages, the court must make an "independent appraisal of the value of the claim" based on a "generous reading of the complaint." See id. A motion to remand must be denied where a reasonable jury could award damages in excess of the federal jurisdictional minimum for the injuries alleged in the complaint. See id.; see also Werwinski v. Ford Motor Co., 286 F.3d 661, 667 (3d Cir. 2002) ("the district court must base its amount-in-controversy determination on what a jury could reasonably award"; affirming denial of remand).

Viewing the allegations of the Complaint under these guidelines necessitates a finding that the amount in controversy requirement has been satisfied. See Shiley, 989 F.2d at 144-46 (affirming denial of remand in medical product liability action where complaint alleged mental anguish, depression, fear of injury and death, and loss of enjoyment of life style and sought expenditures for medical and psychiatric care and punitive damages); Compl. ¶¶ 79, 84-90, 102, 114, 124, 149-51, 155 (asserting entitlement to compensatory and punitive damages for, *inter alia*, mental anguish, permanent injuries, medical and psychological treatment, impaired enjoyment of life, shortened life expectancy, and fear of additional injuries).

Tellingly, Plaintiffs avoid asserting anywhere in their Complaint or remand motion that the amount in controversy falls short of $75,000. Indeed, the remand motion papers do not even *address* amount in controversy. As such, the amount in controversy requirement is not at issue here and should be deemed satisfied. See, e.g., Bertucci v. Lafayette Ins. Co., Civ. A. No. 01-608 Section N, 2001 U.S. Dist. LEXIS 16744, at *15 (E.D. La. Oct. 11, 2001) ("[i]n light of

plaintiff's apparent concession [regarding amount in controversy], the Court finds that the requisite amount in controversy has been established"); Anderson v. Allstate Life Ins. Co., CA 00-0958-C, 2001 U.S. Dist. LEXIS 2603, at *16 n.1 (S.D. Ala. 2001) (finding that removing parties had met burden regarding amount in controversy where damages requested in complaint were not limited and where plaintiff made no argument on amount in controversy). In any event, the Complaint amply demonstrates that Plaintiffs' claimed damages, if proven, meet the jurisdictional minimum.

C. To the Extent There Is Any Ambiguity Regarding This Court's Diversity Jurisdiction, Limited Jurisdictional Discovery Is Appropriate

If there is any uncertainty regarding the untimely nature or value of Plaintiffs' claims, the Court should allow limited jurisdictional discovery into these issues and stay determination on the instant motion. This procedure has been followed by this and other federal courts that have permitted limited jurisdictional discovery in connection with the disposition of motions to remand. See Meier v. Hamilton Standard Elec. Sys., Inc., 748 F. Supp. 296, 298 (E.D. Pa. 1990); Megill v. Worthington Pump, Inc., Civ. A. No. 98-76-SLR, 1999 U.S. Dist. LEXIS 4433, at *3-4 (D. Del. 1999); Potts v. R.J.R. Reynolds Tobacco Co., No. Civ. A. 00-1316, 2001 WL 685996 (E.D. La. June 15, 2001) (allowing defendants 60 days of limited discovery regarding timeliness of plaintiff's claims); Scott v. R.J. Reynolds Tobacco Co., No. Civ. A. 99-3091, 2001 WL 327584 (E.D. La. Apr. 2, 2001) (granting defendants' motion to conduct limited discovery regarding, *inter alia*, statute of limitations, and setting motion to remand for hearing approximately 60 days later).

This Court has granted limited discovery in order to determine whether a claim has been filed outside the applicable statutes of limitation. See Smith v. Berg, Civ. A. No. 99-2133,

2000 U.S. Dist. LEXIS 4513, at *17 n.6 (E.D. Pa. 2000); University Patents v. Kligman, 762 F. Supp. 1212, 1214 (E.D. Pa. 1991). This Court has also considered evidence outside the pleadings in evaluating amount in controversy. See Sdregas, 2002 U.S. Dist. LEXIS 12159, at *5 (noting court may "consider evidence such as depositions, affidavits, and other documentation that is relevant to the value of the claims at issue"); Irving v. Allstate Indem. Co., 97 F. Supp. 2d 653, 654-55 (E.D. Pa. 2000) (noting court's freedom to look beyond the pleadings and consider "stipulations and discovery evidence such as affidavits, depositions, and other documents relevant to the value of the claims"); Kobaissi v. American Co. Ins. Co., 80 F. Supp. 2d 488, 490 (E.D. Pa. 2000) (when considering a motion to remand, the court must turn to the complaint and "appropriate extraneous materials" when determining if the amount in controversy has been met). Thus, to the extent there is any ambiguity regarding the Court's subject matter jurisdiction, there is sound precedent for allowing defendants limited jurisdictional discovery.

II. THIS COURT HAS FEDERAL QUESTION JURISDICTION

A. Plaintiffs' Allegations Concerning OxyContin Confer Jurisdiction on This Court

In assailing Defendants' federal question ground as an independent basis for federal jurisdiction, Plaintiffs erroneously focus on the doctrine of complete preemption. Pl. Mem. at 11-12. However, it is well-settled that a defendant may remove a claim alleged under state law if vindication of that claim necessarily turns on a substantial question of federal law. Franchise Tax Bd. v. Construction Laborers Vacation Trust, 463 U.S. 1, 9, 28 (1983) (even if federal law does not expressly create plaintiffs' cause of action, the federal courts will nonetheless have jurisdiction over the matter if plaintiffs' claim "necessarily depends on resolution of a substantial question of federal law"); Goepel v. National Postal Mail Handlers Union, 36 F.3d 306, 309 (3d

Cir. 1994) (quoting Franchise Tax Bd., 463 U.S. at 22) (a state claim which is "really one of federal law" may be removed to federal court because "it is an independent corollary of the well-pleaded complaint rule that a plaintiff may not defeat removal by omitting to plead necessary federal questions in a complaint").

Here, Plaintiffs' purported state law claims, challenging the labeling practices of Defendants, must be deemed to arise under federal law. They necessarily turn on a construction of federal law, requiring an interpretation and application of the Federal Food, Drug and Cosmetic Act ("FDCA") and federal regulations promulgated by the Food and Drug Administration ("FDA").

Plaintiffs improperly attempt to avoid the federal question presented in the Complaint by disavowing reliance on federal law for their claims. See Pl. Mem. at 12, 14. The existence of a federal question for purposes of subject matter jurisdiction is determined by the nature of the claims asserted and relief sought, however, and not by Plaintiffs' self-serving characterization of their claims. See 14B CHARLES A. WRIGHT ET. AL., FEDERAL PRACTICE AND PROCEDURE § 3722 (3d ed. 1999) (under the artful pleading doctrine, removal may be proper where a federal claim does not expressly appear on the face of the complaint).

Here, Plaintiffs allege that Defendants are responsible for placing a drug that was "likely to cause serious and sometimes fatal side effects" into the stream of commerce, with warnings and labeling – approved by the federal government – that are nonetheless false, misleading, incomplete, defective, and deceptive. See, e.g., Compl. ¶¶ 93, 98, 110, 120, 151; see also Compl. ¶¶ 95(b), 108, 109, 118. Thus, it is apparent that Plaintiffs' allegations directly and

repeatedly challenge the FDA-approved formulation, warnings and labeling of OxyContin. See, e.g., Compl. ¶¶ 35, 48, 50, 93, 95, 98, 99, 107, 109-11, 118-21, 151, 152.[8]

The specific language appearing on the warnings accompanying OxyContin is carefully prescribed by the FDA. Any change in that warning language would require advance evaluation and approval by the FDA under the FDCA, 21 U.S.C. § 301 et seq. Such requests for labeling changes can be granted only by the FDA as a matter of law. See, e.g., 21 C.F.R. § 314.70 (prohibiting a manufacturer from "strengthen[ing] a contraindication, warning, precaution, or adverse reaction" without prior FDA approval). By seeking remand of an action challenging the adequacy of FDA-approved labeling, Plaintiffs are requesting that a *state court* serve as judicial purveyor of new "labeling" for a federally-regulated Schedule II controlled substance. Congress, however, has granted the FDA – and the federal courts for review – *the sole and exclusive authority* to approve all orders relating to the "labeling" of a federally controlled substance. See 21 U.S.C. § 332(a); Bernhardt v. Pfizer, Inc., Nos. 00 Civ. 4042 LMM, 00 Civ. 4379 LMM, 2000 WL 1738645, at *3 (S.D.N.Y. Nov. 22, 2000).

Furthermore, if Plaintiffs somehow succeed in proving such allegations, the likely outcome is that a state court could proceed to order what it deems appropriate injunctive relief – conceivably including court-ordered changes to Purdue's labeling practices. Moreover, as a

[8] Defendants acknowledge, as Plaintiffs stress, that the court declined to exercise federal question jurisdiction in McCallister v. Purdue Pharma L.P., 164 F. Supp. 2d 783 (S.D.W. Va. 2001), another product liability action involving OxyContin. See Pl. Mot. ¶ 14; Pl. Mem. at 12-13. That decision is not binding or controlling here. Moreover, the opinion failed to recognize the expansive definition of "labeling" set forth in Supreme Court precedent and FDA regulations and further erred in not applying the doctrine of preemption to the specific labeling practices assailed by plaintiffs, which constitute challenges that can only be addressed by the federal system. As will be discussed further infra, allegations of Defendants' purportedly wrongful conduct in connection with package inserts and other warnings are in effect challenges to federally-regulated labeling practices and the FDA-approved labeling in this case and, thus, present a federal question.

practical matter, from Defendants' perspective, a damages award would have the same impact as an injunction: it could force Defendants to make product or labeling changes to avoid successive adverse judgments. See, e.g., Cipollone v. Liggett Group, Inc., 505 U.S. 504, 521 (1992) (holding common law damages actions have the same force as other forms of preventative relief and are comparable to state regulation for purposes of preemption). Thus, the relief sought by Plaintiffs would unavoidably compel changes to OxyContin's "labeling," as that term is broadly defined by the FDA, Congress and the U.S. Supreme Court, and thus invokes federal jurisdiction.

The term "labeling," as used in the FDCA and federal regulations and interpreted by the U.S. Supreme Court, is distinguished from the ordinary drug term "label," which refers only to the display of written, printed or graphic matter upon the immediate container of any article. See 21 U.S.C. § 321(k). "Labeling" is defined as "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such Article." 21 U.S.C. § 321(m). The Supreme Court's prevailing interpretation of "labeling" under 21 U.S.C. § 321(m) is that "the phrase 'accompanying such Article' is *not restricted to labels that are on or in the article or package that is transported.*" Kordel v. United States, 335 U.S. 345, 349 (1948) (emphasis added).

> "One Article or thing is accompanied by another when it supplements or explains it in the manner that a committee report of the Congress accompanies a bill. *No physical attachment [of] one to the other is necessary*. It is the textual relationship that is significant."

Id. at 350 (emphasis added). Information pertaining to a drug that is distributed *independently* of the drug constitutes "labeling" under the FDCA. Id. at 347-50 (holding that information about a

drug disseminated *independently* of the drug nonetheless constitutes "labeling"); see also 21 C.F.R. § 1.3 ("labeling" includes "all written, printed, or graphic matter accompanying an article at any time while such article is in interstate commerce or held for sale after shipment or delivery in interstate commerce"). The text of FDA regulations explicitly defines "labeling" to include each of the following:

> "Brochures, booklets, mailing pieces, detailing pieces, file cards, bulletins, calendars, price lists, catalogs, house organs, letters, motion picture films, film strips, lantern slides, sound recordings, exhibits, literature and reprints and similar pieces of audio, video or visual matter descriptive of a drug and references published (for example, the 'Physician's Desk Reference') for use by medical practitioners, pharmacists, or nurses, containing drug information supplied by the manufacturer, packer, or distributor of the drug and which are disseminated by or on behalf of its manufacturer, packer, or distributor . . . ."

21 C.F.R. § 202.1(l)(2). In this case, Plaintiffs' challenges to product labeling unavoidably involve the exclusive jurisdiction of the FDA *as a matter of federal law*,[9] see Kordel, 335 U.S. at 347-50, and thus give rise to federal question jurisdiction.

In addition, Plaintiffs assert claims challenging the decisions of federal agencies vested with the authority to regulate the approval, marketing, and distribution of OxyContin.

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[9] In addition, the federally-regulated nature of Plaintiffs' claims regarding OxyContin cannot fairly be disputed. As Plaintiffs apparently recognize (Compl. ¶ 27), OxyContin is designated a Schedule II prescription drug under the federal Controlled Substances Act (the "CSA"). See 21 U.S.C. § 812(c); 21 C.F.R. § 1308.12(b)(1), (2); 55th Physician's Desk Reference, "OxyContin," 2697–2701 (2001); see also 21 U.S.C. § 355. As a Schedule II prescription drug, every aspect of OxyContin's manufacture, distribution, and prescription is governed by exclusively federal regulations under the CSA and the FDCA. In addition, federal Drug Enforcement Agency ("DEA") regulations expressly limit prescriptions for OxyContin to uses satisfying a "legitimate medical purpose" by a physician who is "acting in the usual course of [his or her] professional practice." 21 C.F.R. § 1306.04(a). Further, physicians must be registered with the DEA – or specifically exempted under applicable DEA regulations – to prescribe controlled substances such as OxyContin. 21 C.F.R. § 1306.03(a).

Plaintiffs, for example, assert that OxyContin is "likely to cause serious and sometimes fatal side effects to users." See, e.g., Compl. ¶ 98. Yet, by approving the New Drug Application for OxyContin, the FDA, pursuant to its authority under the FDCA, specifically found OxyContin to be safe and effective for its approved indications when prescribed by a licensed physician holding a valid DEA registration number and when used as directed pursuant to the FDA-approved prescription information. See 21 U.S.C. §§ 355(a), (b).

In an attempt to obfuscate the issue, Plaintiffs conveniently downplay the extensive role of the FDA respecting OxyContin. The public record, however, confirms that these claims should be regarded as inherently federal and suitable for jurisdiction in this Court. For example, at recent hearings before the Senate Committee on Health, Education, Labor and Pensions, John K. Jenkins, M.D., the Director of the Office of New Drugs, Center for Drug Evaluation and Research ("CDER") for the FDA, explained:

> "OxyContin was reviewed by FDA and was approved for treatment of moderate to severe pain based on two clinical trials that demonstrated that it was safe and effective for this use. Prior to approval, FDA evaluated the benefits and risks of the use of OxyContin for treatment of moderate to severe pain and determined that the drug was appropriate for use in the population when used according to the approved labeling."

Declaration of Edward F. Mannino, dated July 16, 2002, attached hereto as Exhibit "A" (hereinafter, "Mannino Decl."), Exh. 1 at 4. Significantly, during the approval process, the FDA assessed OxyContin's potential for abuse and misuse, which claim is at the core of this Complaint. As Dr. Jenkins stated:

> "At the time of approval, the abuse potential for OxyContin was considered by FDA to be no greater than for other Schedule II opioid analgesics that were already marketed in the U.S.

* * * * *

> [A]t the time of its approval, FDA believed that the controlled-release characteristics of the OxyContin formulation would result in less abuse potential since, when taken properly, the drug would be absorbed slowly and there would not be an immediate 'rush' or high that would promote abuse."

Id. Dr. Jenkins's testimony before the Senate committee brings into sharp focus the federal nature of the "labeling" claims raised by Plaintiffs. It further drives the conclusion that Plaintiffs' challenges to the regulatory process belong in the federal, not state, system.

By challenging the federal regulatory system and provisions described above for this most highly-regulated Schedule II controlled substance, Plaintiffs have indeed alleged claims that are necessarily federal in character and that support the exercise of federal jurisdiction. Where, as here, any claim arises under federal law, the Court may exercise supplemental jurisdiction over the entire action. 28 U.S.C. § 1367.

B. Federal Remedies Exclusively Govern Plaintiffs' Claims

Plaintiffs fail to bring to the Court's attention that there are currently federal procedures for achieving the relief implicitly sought herein. The proper procedure to challenge the adequacy of a drug's existing warnings or labeling is to: (1) commence an action under Section 10 of the Administrative Procedures Act ("APA") for judicial review of the FDA's order approving OxyContin labeling and warnings, see 5 U.S.C. §§ 702, 706, or (2) bring a citizen's petition to the FDA to effect a change in the labeling and warnings accompanying OxyContin, see 21 C.F.R. § 10.30. See, e.g., Buckman Co. v. Plaintiff's Legal Comm., 112 S. Ct. 1012, 1017-18 (2001) (noting that the FDA is "empowered to investigate suspected fraud . . . and citizens may report wrongdoing and petition the agency to take action [pursuant to 21 C.F.R.]

§ 10.30") (citations omitted); Henley v. FDA, 77 F.3d 616, 619 (2d Cir. 1996) (federal judicial review under the APA of the FDA's action in denying a citizen's petition seeking changes in the labeling of a prescription drug); Upjohn Mfg. Co. v. Schweiker, 681 F.2d 480, 483 (6th Cir. 1982) (federal judicial review under the APA of the FDA's action in approving a new drug application).

Thus, the remedy for Plaintiffs' allegations against OxyContin clearly arises exclusively under federal law. "When federal law creates an exclusive remedy for some wrong, displacing any remedy that the states may have for it, a suit to redress that wrong necessarily arises under federal law." Kaucky v. S.W. Airlines Co., 109 F.3d 349, 351 (7th Cir. 1997) (Posner, J.) (denying plaintiffs' motion to remand on the ground that purported state law claims for conversion and breach of contract arose under 26 U.S.C. §§ 6401-02 because they were suits for a tax refund). A suit to redress the alleged wrongs in this case arises under federal law because actions under Section 10 of the APA and citizens' petitions to the FDA evidence "federal law creat[ing] an exclusive remedy for some wrong, displacing any remedy that the states may have for it." Id.

The exclusively federal nature of the relief impliedly sought herein was confirmed by the court in Bernhardt, 2000 WL 1738645. The Bernhardt plaintiffs sought injunctive relief affecting the warnings accompanying a prescription drug. The court stayed the claim, holding that the FDA had primary jurisdiction to make all such determinations with respect to drug labeling, because it had the requisite "expertise":

> "The above review of the relevant regulatory scheme convinces this Court that whether the notice requested by plaintiffs is warranted is a decision that has been squarely placed within the FDA's informed expert discretion."

2000 WL 1738645, at *3. The court noted that the plaintiff, like Plaintiffs here, had available a citizen's petition to request the FDA to take action. Id. Significantly, the court's finding that the FDA has primary jurisdiction entailed that the federal courts necessarily possess subject matter jurisdiction over such actions. The decision in Bernhardt demonstrates that actions affecting labeling are within the exclusive province of the FDA, and therefore are federal in nature.[10]

These principles and authorities compel the conclusion that the challenges made and relief sought by Plaintiffs are truly federal in nature and are within the purview of the FDA. Accordingly, this Court has federal question jurisdiction, and Plaintiffs' motion to remand should be denied.

CONCLUSION

The Court should reject Plaintiffs' transparent efforts to evade federal subject matter jurisdiction and to strip Defendants of their right to litigate in a federal forum. Plaintiffs' Complaint clearly demonstrates that the claims against the non-diverse defendants are time-barred. Plaintiffs have alleged detailed events showing that Mr. Yurcic did discover (or should have discovered) his injuries more than two years prior to the commencement of this case. Indeed, Mr. Yurcic was admitted to a detoxification program and, separately, was placed on a narcotic withdrawal plan. Both actions were in response to his alleged addiction to OxyContin, and outside the limitations period. This Court should not now give any credence to Mr. Yurcic's belated and contradictory attempt to claim that he was not aware of his alleged addiction at those

[10] In fact, on July 25, 2001, the FDA announced that it had approved certain changes to the labeling of OxyContin. See http://www.fda.gov (FDA website announcing changes to OxyContin labeling). In addition, Dr. Jenkins testified before the Senate committee just months ago that the "FDA has worked with Purdue Pharma to implement other specific changes in OxyContin labeling." Mannino Decl., Exhibit "A" at Exh. 1 at 5.

times. Additionally, the amount in controversy requirement is satisfied. Thus, the Court has diversity jurisdiction over this matter. Separately, the Court can elect to exercise federal question jurisdiction based on the Complaint's inherently federal nature and the complex federal framework governing the acts challenged in this matter. The motion to remand should be denied.

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I, Katherine Menapace, Esquire, hereby certify that a copy of the foregoing Joint Memorandum of Law in Opposition to Plaintiffs' Motion to Remand was mailed to the following by regular U.S. mail, postage prepaid, this 16th day of July, 2002:

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